PROJECTPLAN

In society today, mental health problems, specifically stress-, anxiety- and depressive disorders, are a primary cause of long-term sick leave, leading to significant societal costs and suffering [1]. One important issue hindering implementation of successful treatments is that there is a marked co-occurrence *between* these problems and somatic health problems, such as different types of pain. For example, in a Swedish primary care study mapping reasons for healthcare visits, 20% of those who sought care for pain stated explicitly that they also sought care for mental health problems [2]. In addition, another 20% reached clinical cut-offs for anxiety and depression while seeking care for pain and not explicitly for mental health problems. As another example, in a Swedish general population study investigating commonalities between stress, pain and sleep, we found that, among those indicating their primary problem as 'stress', 60% also reported problems with pain and sleep [3]. Thus, patients with mental health problems typically also have somatic health problems.

The comorbidity between mental health and somatic problems has serious adverse consequences. Typically, the allocation of patient-to-treatment is based on the identification of a 'primary' problem area, disregarding this significant group of patients with concurrent emotional and somatic problems. In our system of healthcare, patients with mental and somatic health problems do not fit the template of psychiatry or pain rehabilitation, and primary care has difficulty integrating and coordinating the input of various health care providers that may become involved. These systemic issues enhance the development of problems rather than alleviate them.

An important key to solving this problem is to develop a more integrated conceptualization of, and treatment model for, these patients' health problems. Current advancements in the fields of emotion science and clinical psychology may provide direction. Specifically, one way to understand the co-occurrence between mental and somatic health problems is offered by the 'transdiagnostic' perspective ([4, 5]; figure 1). This perspective focuses on key emotion regulation processes that maintain and contribute to the exacerbation of both mental and somatic health problems [6]. With respect to stress, anxiety, depression and pain this means that, instead of the one being a consequence of another, the co-occurrence is explained by the (over) activation of basic emotion regulatory processes such as worry, rumination, emotional suppression and avoidance behaviors. Also, sleep is thought to play an important role, interacting with both mental and somatic health problems [24, 25].

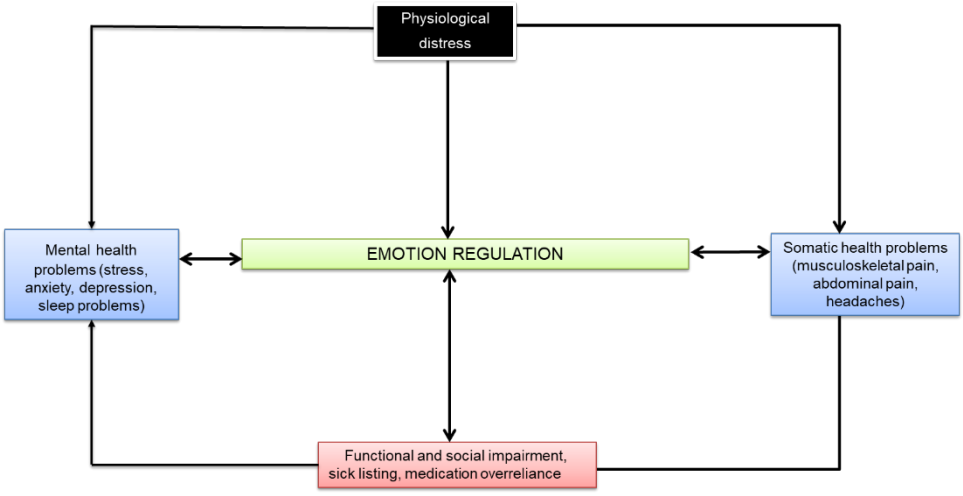

Figure 1. A transdiagnostic view of the relation between mental and somatic health problems. Adapted from [7].

This perspective on comorbidities has gained considerable empirical support in the literature [8, 9]. Hence, treatments that focus on these common regulatory mechanisms can be an opportunity to treat comorbid problems and thus be more effective and parsimonious for this patient group.

Based on these theoretical developments, we have systematically developed a new treatment model that specifically targets underlying emotion regulation problems. This hybrid emotion-focused treatment combines exposure methods from cognitive behavior therapy (CBT) with an emotion regulation approach informed by procedures in Dialectical Behavior Therapy (DBT). Exposure is a state-of-the-art CBT method that aims to tackle functional impairment through systematic and gradual approach of feared and avoided activities [eg. 10, 11]. However, as exposure requires that the patient has skills to manage fear-provoking situations, it may insufficiently address the needs of patients with high levels of emotional distress. Emotional dysregulation needs more specific therapeutic attention for these patients to benefit from exposure practices [12]. DBT is such a treatment approach, originally developed for chronically suicidal patients [13] but thereafter successfully adapted for patient groups with other complex problems characterized by high degrees of emotional dysregulation. It centers on teaching patients emotion regulation skills in a context of non-judgmental acceptance and desired goal pursuit. Patients are trained to accurately identify, understand, sooth and effectively act upon their emotional responses to aversive stimuli by means of a range of techniques [14].

The hybrid emotion-focused treatment integrates procedures from exposure and DBT with a clear uniting conceptualization focused on targeting underlying processes that maintain co-occurring mental and somatic health problems. After initial feasibility studies, we recently confirmed the efficacy of this treatment in a randomized controlled trial against an active comparison group, consisting of standard CBT methodology [15]. After 10-16 sessions, patients suffering from longstanding debilitating pain *and* high levels of anxiety and depression achieved significantly better results on key outcomes such as function and depression. Furthermore, we found that changes in the ability to regulate pain and emotion mediated the effects of treatment, supporting the transdiagnostic theoretical underpinnings of the treatment model [26]. As a next step, this treatment's effectiveness needs to be tested, broadening the target group to focus on patients with mental health problems comorbid with somatic problems and delivered by clinicians in 'real world' clinical contexts. Methodologically, we propose using replicated single-case experimental AB designs with randomized baseline lengths. Participants will be followed using repeated and randomized measurement of key variables across both phases. This design allows for solid effectiveness testing using randomization tests, will provide, detailed information on individual variation, and also allows the probing of mechanisms of change when aggregated across patients [17, 18]. Included in the design is also standardized pre-post and follow up measurement allowing for single group analysis of change. In addition, we propose to add qualitative assessment from practitioners, detailing how the treatment and its implementation are experienced.

Aim: The aim of this project is to implement and evaluate the effectiveness of a transdiagnostic emotion-focused treatment protocol in clinical context. The treatment addresses comorbid mental (stress, anxiety- and depressive) and somatic health (pain)

problems and targets core emotion regulation processes that are hypothesized to maintain and exacerbate these problems.
Specific question: Do the effects of the transdiagnostic emotion-focused treatment generalize when delivered within first line clinical care and when addressing a variety of problems within the spectrum of stress, anxiety, sleep, depression and pain problems?
Hypothesis: The treatment model is feasible to apply in clinical care and leads to a decrease in emotional symptoms, medication use and sick leave and an increase in functional ability.

Relevance
This proposal provides a unified treatment approach to a complex area characterized by symptom heterogeneity, often very debilitating problem levels, and long-term sick leave. This approach will provide clinicians with a parsimonious treatment approach and patients with tools that will strengthen their ability to adaptively cope with symptoms, improve functioning in daily life and decrease sick leave. Moreover, it will provide valuable theoretical knowledge on the interaction between mental and somatic health problems.

METHOD

Design

This study uses a replicated Single Case Experimental Design (SCED). Patients eligible for the intervention will be randomly assigned to a baseline phase length of 14 to 28 days prior to treatment start, during which they will fill out a weekly diary on symptoms, function and emotion regulation. Patients will continue to fill out this diary during treatment, and for a 7-day period at 1-year follow-up. This design addition will allow for repeated observations at different levels of the independent variable (e.g., baseline A vs. treatment B) and an analysis of individual variations in treatment effects. Recent statistical advances support aggregation of this type of data across subjects, allowing for more advanced moderation analyses [18]. Using a design where each participant receives the active treatment, after a randomly chosen length of waiting solves the ethical dilemma of withholding active treatment and provides a built-in replication, which is of special importance in effectiveness-implementation studies since it rarely occurs and frequently fails [20].

Selection

A series of N=5 replications within each treatment location across a series of N=10 different treatment locations results in a total number of 50 AB replications. Patients will be recruited and treated at primary care and rehabilitation centers in our network (see under contacts and cooperations for details). *Inclusion criteria are:* 1. A clinical degree of mental health problems (defined as >11 points (cut-off for a definite case) on at least one of the two subscales (anxiety and depression) of the Hospital Anxiety and Depression Scale [21] and somatic health problems (chronic musculoskeletal pain, abdominal pain and/or headaches (> 3 months duration)) 2. Functional impairment in daily life due to somatic symptoms (defined as > 20 points on question 21-24 of the Örebro Musculoskeletal Pain Questionnaire [22] and/or > 3 on question 2 (‘How much are your daily activities influences by your pain?’) of the Multi Dimensional Pain Inventory. *Exclusion criteria are:* 1. Severe psychiatric disorders that may require immediate other treatment (alcohol abuse, bipolar disorder, psychotic

disorders, severe depression), 2. Currently already receiving psychological treatment, 3. Recently been started on psychopharmacological treatment for depression and/or anxiety (cut off criterion: < 3 months prior to planned treatment start), 4. Insufficient mastery of the Swedish language written as well as spoken.

Procedure

Providers (e.g. physicians, psychologists, physical therapists, nurse practitioners) at primary care and rehabilitation centers will refer patients to the study during initial or follow-up clinic visits or via an information letter send by regular mail. Patients will receive a brochure that describes the study and includes contact information to the providing clinician at the center (the treating psychologist) as well as to the study team at Örebro university.

The providing clinician coordinates the screening (checks for inclusion and exclusion criteria), provides the patient with written and verbal study information and will send a completed eligibility checklist and informed consent for each patient via a secure digital system to the study team. Additionally, study information will be available in waiting rooms, on information boards and on clinics' websites for patients to self-refer to the study. For each patient eligibility for enrollment will be verified by the study team via a brief follow up screening phone call. During this call, eligible participants will be provided with details on how to fill out the digital baseline assessment. After screening and baseline assessment, participants will be randomly assigned to a 14, 21 or 28-day baseline diary assessment before commencing treatment. The hybrid treatment will be conducted by a mini team of a medical doctor (ensuring adherence to medical guidelines), licensed clinical psychologist (main responsibility for the treatment) and a licensed physiotherapist (providing assessment and treatment support in exposure for physical activities). As shown to be important [23], the psychologist will also, when applicable, address and integrate the treatment with the workplace.

Description of the transdiagnostic emotion focused treatment
The following is a short overview of the main stages in the treatment (adapted from [15]).

Treatment stages
I. Building a working relationship, soothing distress and developing relevant goals
II. Developing skills to prepare for exposure and improve regulation of emotions and somatic symptoms in everyday life
III. Exposure for emotions and activities
IV. Training context sensitivity; applying regulatory skills in the context of interpersonal relations
V. Maintaining and refining skills into the future

Table 1. A short overview of the hybrid emotion focused treatment.

Materials
Demographic data regarding age, gender, country of birth, relationship status, education, occupational status, medication use (psychopharmaca, sleep and pain medication) and somatic symptoms (location, duration, intensity, frequency of pain) will be gathered. A battery of standardized and psychometrically validated questionnaires covering the following areas will be distributed before and after treatment and at 1-year follow-up: emotional problems (stress/ exhaustion symptoms, anxiety and depressive symptoms as well as diagnostic criteria for psychiatric disorders based on DSM-V, sleep problems, functional impairment in daily life, quality of life, sick leave, perceptions of the work environment, and emotion regulation processes. Targeting the involved clinicians, we will perform a qualitative concurrent and retrospective process evaluation to identify what may influence the conduct and quality of the implementation (using semi-structured interviews). Targeting patients, we will furthermore assess implementation outcomes through data on treatment expectancy, adherence, and satisfaction. Self-report data at follow-up on sick leave and medication use will be complemented with data from the national social insurance agency, the patient registry and the national prescription registry.

Contacts and cooperations
This project will be conducted within the context of primary health care and rehabilitation centers in Sweden (Specifically, university hospital pain rehabilitation clinics in Örebro, Stockholm, Lund and Linköping and primary care units in Region Dalarna and Örebro, including private primary car clinics. Additionally primary care and pain rehabilitation clinics in the following regions will be involved: Skåne, Kronoberg, Värmland, Västra Götaland, Gävleborg, Västerbotten, Dalarna, Västmanland, and Östergötland). Clinicians (psychologists, physiotherapists, and medical doctors) will be trained in delivering the protocol. Training and implementation will be conducted by the study team from the Center for Health and Medical Psychology (CHAMP) at Örebro University. CHAMP is an established research environment that focuses on the study of psychological factors in the development, prevention, and treatment of disability due to health psychological disorders.

Data management and communication plan
This trial is preregistered at clinicaltrial.gov (NCT05082922) and received ethical clearance from the Swedish Ethical Review Authority (2020-06083; 2021-02909; 2021-04534). Data

management (e.g. secure handling and registration of personal information; registration of all comprehensive material, secure storage of all data and personal information) will follow Örebro University's and European Union guidelines. The results will be published in international peer-review journals and presented at international conferences. The results will be reported to the primary care and rehabilitation clinical community and the treatment protocol will be made available for clinical application through publication of a treatment manual and training of clinicians. Lay and media presentations will be provided as will information be distributed via a webpage on the research center's website.

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